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| 10/035,831 | 12/28/2001 | William P. Van Antwerp | 047711-0273 | 1788 |
| 7590 | | 11/01/2007 | EXAMINER | |
| Irvin C. Harrington, III | | BOUCHELLE, LAURA A | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/035,831

Applicant(s)

VAN ANTWERP ET AL.

Examiner

Laura A. Bouchelle

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9-27,68,69 and 87-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-27,68,69 and 87-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/042138 and 09/324783, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Both applications fail to disclose a layer that reduces diffusion of small molecules *through* the tubing, both only disclose a material that reduces absorption of materials. Both applications fail to disclose that an insulin formulation is maintained in the tube. Furthermore, both applications fail to disclose the layers formed of the materials required by claims 1, 3 and 26. If applicant believes that this is in error, please point to the portions of the prior applications that provide adequate support for the instant claims.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 2, 7, 9-25, 68, 69 87-89, 98-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 5702372) in view of Ash et al (US 6042561).

4. Nelson discloses a lined infusion catheter comprising a layer that reduces diffusion of small particles through the tube, wherein the layer is formed of PTFE or polyurethane (Col. 4, lines 8-15). The catheter comprises an outer layer formed of silicone (Col. 1, lines 5-10). Nelson teaches a lined infusion catheter comprising a liner made of Teflon that is relatively nonporous to prevent contaminants such as carbon dioxide from diffusing into the lumen and denaturing the insulin (Col. 4, lines 9-15). Adjusting the porosity and thickness of the liner is inherently capable of reducing the diffusion of contaminants any amount.

5. Claims 1, 2, 68,69 differ from Nelson in calling for the insulin formulation to be maintained in the tubing. Ash teaches an infusion device comprising a continuous insulin infusion pump wherein the insulin is maintained in the tubing since the delivery is continuous (Col. 1, line 63 – Col. 2, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Nelson to maintain the insulin formulation in the tube as taught by Ash to prevent occlusions or deposits from forming in the tubing.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Brange et al (US 4472385). Claim 3 differs from Nelson in calling for the insulin formulation to be stabilized by being substantially free of deposits or occlusions comprising insulin and an excipient. Brange teaches stabilized insulin preparation comprising highly purified insulin and an excipient to provide the maximum concentration and stability (Col. 3, lines 45-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include in the device of Nelson the insulin formulation of Brange so that the insulin has maximum stability.

7. Claims 4-5 rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Ash, in further view of Brange. Claim 4 differs from the teachings above in calling for the insulin to be a high concentration formulation. Claim 5 calls for the formulation to be greater than about 100 U/ml. Brange teaches a stabilized insulin preparation comprising a high concentration formulation of insulin at a concentration of 40 to 1000 U/ml (Col. 3, lines 50-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the insulin formulation of Nelson to be of a concentration greater than about 100 U/ml as taught by Brange to achieve the optimal concentration.

8. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Ekwuribe et al (US 6309633). Claims 26 and 27 differ from Nelson in calling for the protein to be the insulin analogue Lispro. Ekwuribe teaches the use of the insulin analogue

Art Unit: 3763

Lispro in the place of insulin because Lispro has a more precise action profile than human insulin (Col. 14, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Nelson to have Lispro as taught by Ekwuribe because Lispro has a more precise action profile than human insulin.

9. Claims 90- 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Van Antwerp et al (US 6443942). Claims 90, 96 differ from the teachings above in calling for the protein compatible material to contain a PEG moiety. Van Antwerp teaches a medication device with protein stabilizing surface coating wherein the coating includes a PEG moiety that promotes the maintenance of the specific protein's native state (Col. 6, lines 55-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Nelson to include a layer containing PEG moiety as taught by Van Antwerp to promotes the maintenance of the specific protein's native state.

Response to Arguments

10. Applicant's arguments filed 8/10/2007 have been fully considered but they are not persuasive.

11. Applicant argues that since Patent No. 5,702,372 and the instant application have a common assignee the rejection under 103(a) improper under 103(c). However, the applications to which the instant application claims priority fail to show adequate support for the instant claims, and therefore, the instant application does not gain the priority date of those prior

Art Unit: 3763

applications. Therefore, the effective filing date of the instant application is 12/28/2001, and the Nelson Patent No. 5,702,372 is a 102(b) reference. The 103(c) traversal does not apply.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763



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